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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,164	08/30/2005	Jerome Tauzin	LOM-43	5234

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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
10/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No.	Applicant(s)	
	10/519,164	TAUZIN ET AL.	
	Examiner	Art Unit	
	MAURY AUDET	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-15* is/are pending in the application.

4a) Of the above claim(s) *8,13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,9-12 and 15* is/are rejected.

7)☒ Claim(s) *7, 9-12 and 15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

As noted previously, the present application has been transferred from former Examiner Young to the present Examiner.

Applicant's amendments to the claims including newly added claim 15 and arguments, are acknowledged. Due to the new grounds of rejection the present application is being sent Non-Final. The Examiner extends an apology to Applicant for the delay in processing of the action to applicant's last response. The action had been returned for a correction, wherein the Examiner, upon review, found it necessary to modify the rejection/objections of record, in order that the record be complete. Due to extenuating circumstances, the Examiner was unable for some time to return to processing the action for mailing. The Examiner extends an open Interview Invitation at any time, to Applicant upon receipt hereof, in order to expedite prosecution towards allowable subject matter.

As stated in the previous action, in part, the elected invention was actually a fraction comprising SEQ ID NOS: 5, and 8-10, as this Examiner misinterpreted the previous Examiner's rejoinder of claims and indication of SEQ ID NO: 5 as the elected "species", which it was not. **The Group and rejoinder of claims (other groups) remain drawn to SEQ ID NOS: 5 and new claim 15 to SEQ ID NOS: 8-10, as the invention (not species). Based on the election, the current claim set remains quite confusing, being drawn to numerous peptides not grouped or elected.**

Group XIX, SEQ ID NOS: 5 and 8-10, was and remains the elected group. The previous examiner then rejoined claims 1 and 2, drawn to a pharmaceutical composition and

method of making, a peptide selected from the group consisting of SEQ ID NOS: 5 and 8-10. Claim 7 (pharmaceutical composition comprising at least two peptides selected from the group consisting SEQ ID NOS: 5 and 8-10), and claims 9-12 (a food product composition comprising at least two peptides selected from the group consisting), are examined on the merits as drawn to SEQ ID NOS: 5 and 8-10. Claims 8 and 13-14 are withdrawn from consideration, as depending from cancelled claims.

The restriction requirement is maintained as FINAL. SEQ ID NOS: 1-4 are required to be cancelled from the claims.

Claim Objections

Claim 11, line 4 is newly objected: after the term "obtaining" the term --a-- needs to be inserted for grammatical correctness.

Claims 7, 9-12, and new claim 15 remain objected to because of the following informalities:

The claims have not been amended commensurate in scope with the elected invention. Namely, SEQ ID NOS: 5 and 8-10. Other non-elected SEQ ID NOS: remain therein, namely SEQ ID NOS: 1-4, which are required to be deleted from the claims. Were the claims so amended, they would likely receive favorable consideration.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112 1st Scope of Enablement* - Vacated**

The rejection of claims 7 and 9-12 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a food product comprising a combination of two or more of SEQ ID NOS: 5 and 8-10, does not reasonably provide enablement as a combination food product for ACE inhibition [or a pharmaceutical composition for treating hypertension], is vacated. Applicant's arguments have been considered and are found persuasive. Namely, based on the arguments on page 6 of the response:

Applicants submit that this contention is misplaced inasmuch as the present specification (for example, the paragraph bridging pages 9 and 10) expressly teaches that "peak No. 4 containing the peptides FPQYLQY (SEQ ID No. 4) and **FALPQYLK (SEQ ID No. 5)**, peak No. 3 containing the peptide FALPQY (SEQ ID No. 3), and peak No. 1 containing the peptide TVY (SEQ ID No. 1) **inhibit ACE at more than 70% (emphasis added)**." As such, the specification clearly provides an enabling disclosure for the use of the claimed products and/or compositions in a manner recited in the claims. Additionally, since the Office Action fails to provide any evidence on lack of enablement of the claimed products, the contentions of lack of enablement are without legal merit.

The instant specification describes a role of ACE in the etiology of hypertensive disorders. For example, see, the paragraphs bridging page 1 and 2 of the instant specification, as originally filed. It is described therein that ACE has a key role in vivo in regulating arterial pressure and that ACE inhibitors (captoproil, benazepril, enalapril, lisinopril, etc) are one of the main classes of molecules used for combating hypertension. Mechanisms via which ACE regulates atrial pressure, for example, via the rennin-angiotensin system, was appreciated in the field well before the filing date of the instant application. This is clear from the referenced scientific publications by Weber et al. and Piepho et al., the abstracts of which were furnished to the PTO. The Examiner is cordially requested to review the disclosure contained in these scientific abstracts.

It is respectfully submitted that the mere presentation of a rationale for the use of ACE inhibitors having the claimed pharmacological activity (for example, ICs0 of 60btM or less) and information pertaining to the methods for using such, coupled with a disclosure of the molecules having such activity, is sufficient for enablement. The rationale for the claimed end uses is clearly presented in Applicants' specification. See, for example page 2, lines 6-15 of the originally filed specification.

The rejection previously stated:

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The rejection of claims under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is maintained for the reasons of record, based on #1 below, as fully described in the earlier action by the previous Examiner, but now applying equally to SEQ ID NOS: 8-10. The former Examiner's 4-page detailed explanation as to why the elected SEQ ID NO: 5 is enabled as a food product, but not enabled for e.g. treating hypertension, or even clearly established for its underlying pathway of ACE inhibition.

Thus, the rejection of the claims as lacking enablement for the following reasons is maintained:

None of elected SEQ ID NOS: 5 or 8-10 has been established as capable of treating hypertension (e.g. claim 11), nor one of it's underlying pathways - as capable of inhibiting ACE (e.g. claims 7 and 9-10, 12).

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and new claim 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 7, the phrase "acceptable vehicle" is unclear. What may constitute an "acceptable vehicle" may be anything that can carry something else, which may not be suitable for use in a pharmaceutical composition. It is suggested that applicant adopt his language in claim 11 to a "pharmaceutically acceptable vehicle" and the amend claim 7 thereto.

Allowable Subject Matter

Claims 7, 9-12, and 15, as drawn to a composition/product combination comprising SEQ ID NO: 5 and any of SEQ ID NOS: 8-10, were not found to be reasonably taught or suggested by the prior art of record. Although there is art on peptides comprising any one of the 4 peptides, there was not found art on a 'combination' (or fraction) thereof.

As noted in the previous action:

The prior art of record was not found to reasonably teach or suggest the combination of any two or more of SEQ ID NOS: 5 and 8-10. Individually only, Garault et al., 2002 (J. Biol. Chem. 277(1): 32-39), is deemed the closest prior art of record. Garault et al. teach the present peptide sequence of SEQ ID NO: 5, FALPQYLK, of casein-alpha-s2, in Table II, page 36. As well as present peptide sequence of SEQ ID NO: 8, ALNEINQFYQK, of casein-alpha-s2, also in Table II, page 36. [The previous Examiner also indicated SEQ ID NO: 9, ALNEINQFY, was taught therein, but this fragment of SEQ ID NO: 8 was not found by the present Examiner therein. However, Garault et al. does not teach or suggest the combination of presently claimed SEQ ID NO: 5 and 8, or any other combination.

Were the rejections/objections above addressed to be overcome, the claims, if amended commensurate in scope to delete SEQ ID NOS: 1-4 and amend SEQ ID NOS: 8-

10 in the base claims, the claims would likely receive favorable consideration, pending the updated search of the art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Maury Audet/
Examiner, Art Unit 1654